REMARKS

Claims 1 and 5 have been amended to state that Applicants' method of treating sexual dysfunction requires oral administration. The amendment has been made to expedite prosecution and Applicants emphasize that they do not agree with the rejections in the Office Action dated January 8, 2003. The above amendments have accordingly been made without waiver or prejudice to Applicants' right to file one or more divisional or continuation applications directed to subject matter now outside the claims by virtue of the amendments.

The claims continue to be rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-36 of co-pending Application No. 08/549,792, in view of Beretta et al. (Medline Abstract, AN 94136073) and Chancellor et al. (Medline Abstract, AN 94182317). As noted in Applicants' previous response, co-pending Application No. 08/549,792 issued on October 22, 2002 as US patent No. 6,469,012.

The claims continue to be further rejected under 35 USC 103(a) as being unpatentable over WO 94/28902 in view of Beretta and Chancellor. The rejection is analogous to the double patenting rejection, except that in place of the application 08/549,792, the WO, which is the published version of the corresponding European application, has been substituted.

The Examiner is urged to reconsider his/her position in view of the claims as now amended, on the basis that the rejection is clearly based on hindsight and that the references have been improperly combined, as discussed below. The claims now specifically require that the mode of administration is oral, as disclosed, for example, in applicants' specification at page 6, line 25. Both the obviousness type double patenting rejection and the obviousness rejection under 35 USC 103(a) appear to be analogous as stated above. Thus, Applicants' arguments in traversal of the obviousness-type double patenting rejection apply equally to the obviousness rejection itself.

Applicants' claimed invention requires that administration for the treatment of sexual dysfunction in an animal with an injured spinal cord be oral and that the treatment employ a compound of formula (I). In the absence of

Applicants' specification (which, of course, may not be used against applicants), one of ordinary skill in the art would not combine either US 6, 469, 012 or WO 94/28902 with either of the secondary references, Beretta and Chancellor. The secondary references disclose different compounds applied topically. It is submitted that one interested in treating a particular condition (sexual dysfunction) through the oral administration of a compound of formula (I) would not find it obvious to do so from references which disclose different compounds administered by different routes. The Chancellor and Beretta references amount to simple anecdotal accounts of the effectiveness of minoxidil and papaverine in the treatment of erectile dysfunction in SCI men. The Chancellor and Beretta compounds are different from the compounds to which Applicants are limited. Neither minoxidil nor papaverine is related to sildenafil to which claims 5-8 and 10 are limited and, as previously noted, neither of them makes any suggestion with respect to any other compounds outside minoxidil and papaverine.

Moreover, at least one of the secondary references teaches away from using the compounds disclosed therein for the treatment of erectile dysfunction. Chancellor states in reference to minoxidil that:

> "All patients were able to achieve only a poorly sustained reflex erection that was inadequate for satifactory intercourse...Minoxidil induced no change in rigidity (range 0-15%)...Both subjective and objective erectile responses to minoxidil were poor..."

Regardless of the results reported for papaverine, Beretta and Chancellor did not disclose or remotely suggest anything applicable in respect of Applicants' claims which feature different compounds administered by a different route. As discussed in previous responses and as repeated below, the prior art must suggest that which applicants have invented and must supply an expectation of success. Beretta and Chancellor do neither, and in fact lead away from the invention by means of the negative results reported for minoxidil by Chancellor.

Applicants position is accordingly that Applicants' claimed invention is not obvious from the claims of US 6, 469,012 or the disclosure of WO 94/28902 taken together with secondary references that disclose (1) different compounds (2) administered by different routes and (3) which may not even be effective. Because of the differences in compounds and in the route of administration, it is

submitted one of ordinary skill would not combine US 6,469,012 or WO 94/28902 with either secondary reference in the first place. Because of the lack of an expectation of success (indeed, because of the negative results reported in Chancellor), one would not find the claimed invention obvious.

For the reasons given above, the Examiner has not established a prima facie case of obviousness, either under §103 or in the sense of obviousness type double patenting. It is further submitted that the combination of references can not even rise to the level of making the invention "obvious to try", and that in any case (as applicants stated in their previous response), the law is very clear in respect of "obvious to try" and of references such as Beretta and Chancellor. To be effective in supporting an obviousness rejection, the references must somehow (1) suggest doing that which Applicants have done and (2) provide a reasonable expectation of success. If they do not, then the best one can say is that they may (or may not) render an invention "obvious to try". The law is emphatic that "obvious to try" is NOT the test of obviousness under 35 U.S.C. §103. American Hospital supply Corp. v. Travenol Laboratories, Inc., 223 USPQ 577, 582 (Fed. Cir. 1984). The Federal Circuit has explained the proper test:

> The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out **and would have a reasonable likelihood of success**, viewed in light of the prior art. **Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure** (emphasis added).

In re Dow Chemical Co., 5 USPQ.2d 1529, 1531 (Fed. Cir. 1988); Amgen, Inc. V. Chugai Pharmaceutical Co. Ltd. 18 USPQ.2d 1016. 1022-23 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991). Neither a suggestion of Applicants' method nor any likelihood of success (i.e., of providing any benefit) would be expected based on the primary references combined with Beretta and/or Chancellor.

Clearly, for the reasons previously stated, the references are insufficient to support the rejection. It is accordingly respectfully requested that the rejection be withdrawn.

In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

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